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Dockets Management Branch (HFA-305)
Food and Drug Administration,
5630 Fishers Lane, rm. 1061
Rockville, MD 20852.
Docket number 99D-0557)
To Whom It May Concern:

1506 '99 MAY 10 10:23

I have chosen to send this letter from a letter writing service. I chose it because it represents my views and opinions perfectly. It is however, signed by me as an individual, and I hope you will consider it as such.

On April 6th, the FDA published a 'Guidance for Industry' in the Federal Register on "Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans." In it, the FDA again acknowledges the dangers of using nonhuman primates as donors in xenotransplants.

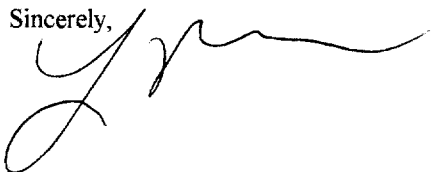
Bottom line: "clinical protocols proposing the use of nonhuman primate xenografts should not be submitted to the FDA until sufficient scientific information exists addressing the risks posed by nonhuman primate xenotransplants."

Essentially, FDA is saying that it would not approve any primate xenografts at this time, but is encouraging further research on primates to study virus transmission to humans. FDA is NOT ruling out other species, like pigs however, in xenotransplants.

- 1) Responsible health authorities would ban all xenotransplants outright, regardless of the species, particularly because of the threats of inter-species virus transmission. (See www.crt-online.org for other reasons).
- 2) Pigs are being considered as the source animal of choice for xenotransplants. But there is no evidence that pigs are any safer than nonhuman primates. We have plenty of evidence that pig viruses would be just as dangerous as nonhuman primate viruses (i.e. influenza, PERVs, paramyxovirus, and earlier this year, the Nipah (Hendra-like virus) in Malaysia that has resulted in hundreds of human infections, 98 human deaths, and 640,500 pigs slaughtered since March 20th).
- 3) The US should follow Europe's lead. In January 1999, the Council of Europe, representing 40 European countries, recommended a world-wide ban on xenotransplants.
- 4) There are safer and more humane alternatives to xenotransplantation that are not being explored by regulatory authorities. These include aggressively promoting preventive medicine, and increasing human organ donation rates as many European countries have successfully done through various legislative schemes.
- 5) The US General Accounting Office published a report on Organ Donation in April 1998 which revealed an untapped donor pool of 150,000 people in the US. The Department of Health and Human Services should fully investigate the points made in that report before allowing xeno-transplants to go forward.

Please carefully consider the points made in this letter.

Sincerely,

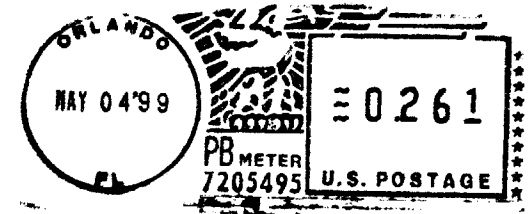


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